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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	**DOMINGUES ET AL.**	**Examiner: Wong, Leslie A.**	
Serial No.:	**10/771,859**	**Group Art: 1794**	
Filed:	**February 3, 2004**	**Docket No.: P5630USA-D1**	
For:	**FOOD PRODUCTS WITH BIOCONTROL PRESERVATION AND METHOD**	**(PIL0009/US/2)**	

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Mary C. Deutsch
MARY C. DEUTSCH

APPEAL BRIEF

Dear Sir or Madam:

This Appeal Brief is being submitted in support of an Appeal from the Final Rejection mailed July 7, 2008, in connection with the above-identified patent application.

A Notice of Appeal was filed on October 15, 2008, and received in the U.S. Patent Office on October 20, 2008, with the required fee of $540.00 for the Notice of Appeal.

Enclosed is a check in the amount of $540.00 for filing this Appeal Brief. It is believed that no other fee(s) are required in filing this paper. However, if any other fee(s) are required, then Appellants hereby authorize such fee(s) therefore to be charged to the Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

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I. Real Party in Interest

General Mills Marketing, Inc., the assignee of record, is the real party in interest.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of Claims

Claims 1- 10, 12-23 and 31-36 are pending. Claims 11 and 24-30 have been cancelled. Claims 1- 10, 12-23 and 31-36 stand rejected. Claims 1- 10, 12-23 and 31-36 are on appeal.

IV. Status of Amendments

No claim amendments have been submitted subsequent to the Final Office Action dated July 7, 2008. A Response Under 37 CFR 1.116 was filed on September 16, 2008, and was considered by the Examiner. However, the request for reconsideration was not found to place the application in condition for allowance.

V. Summary of Claimed Subject Matter

Note: the parenthetical citations below refer to the Applicants' specification and figures.

The specifically claimed subject matter of independent claim 1 is supported and described in the subject application as follows:

1. A food product comprising a pasteurized (p. 8, lines 9-12; p. 14, line 30 – p. 15, line 1) hydrated, edible food item (p. 7, lines 21-26), said food product being at a temperature state of less than 10 ° C (p. 15, lines 2-9), wherein said stored food product comprises encapsulated (p. 9, lines 25-27), dormant, hydrated (p. 10, lines 12-14; p. 11, lines 23-24; p. 16, lines 20-22) nontoxic microorganisms that are effectively dormant up to temperatures of about 10 ° C. (p. 12, lines 23-29; p. 16, lines 29-31), and wherein, if the food product reaches a temperature above 10 ° C. (p. 17, lines 12-13), said nontoxic microorganisms (p. 3, lines 18-20; p. 7, lines 22-23) release by-products into said food product that inhibit the growth of harmful microorganisms (p. 17, lines 14-26).

The presently claimed invention is directed to a food product comprising a pasteurized hydrated, edible food item at a temperature state of less than 10 ° C. (p. 7, lines 21-26; p. 8, lines 9-12; p. 14, line 10 – p. 15, line 1; p. 15, lines 2-9). The food product comprises encapsulated, dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10 ° C. (p. 9, lines 25-27; p. 10, lines 12-14; p. 11, lines 23-24; p. 12, lines 23-29; p. 16, lines 20-22, 29-31). If the food product reaches a temperature above 10 ° C., the nontoxic microorganisms release by-products into the food product that inhibit the growth of harmful microorganisms (p. 3, lines 18-20; p. 7, lines 22-23; p. 17, lines 12-26).

By the presently claimed invention, food products can be produced that are protected against potentially harmful microbial growths by including viable nonharmful bacteria or microorganisms in the food products (p. 5, lines 21-22). In particular, dried bacteria are used in formulating biocontrol agents such that at least a portion of the dried bacteria remain sufficiently dry during cooking and/or

pasteurization processing of the food (p. 5, lines 22-25). The bacteria form a starter culture for the growth of and acid production by the bacteria within the food product under conditions that permit the growth of potentially harmful organisms (p. 5, line 28 – p. 6, line 2). If a heating step is involved in the food preparation, the bacteria generally have to be protected from inactivation by the heat processing of the food product prior to a packaging step (p. 6, lines 11-17). It has been discovered that the preservation of the desired microorganisms can be promoted by maintaining at least a portion of the microorganisms in the dry state during periods when the added cultures are subjected to high temperatures (p. 11, lines 17-20).

The bacteria are selected such that they will successfully inhibit the growth of potentially pathogenic or toxin producing bacteria if the food product is temperature abused (p. 7, lines 1-3). The growth of the selected microorganisms helps to inhibit the growth of pathogenic organisms because of competition (p. 7, lines 9-10). The selected microorganisms may also produce by-products that inhibit the growth of harmful microorganisms (p. 7, lines 10-11). The by-products in some embodiments are acids, which lower the pH of the food product (p. 17, line 28 – p. 18, line 12). Alternatively, the microorganisms may produce one or more antibiotics (p. 13, lines 26-27).

The microorganisms may comprise a bacteria belonging to a genera selected from the group consisting of *Lactococcus, Streptococcus, Leuconostoc, Pediococcus, Lactobacillus, Bifidobacterium*, and *Propionibacterium* (p. 13, lines 6-11). The microorganisms may comprise a bacteria such as *Pediococcus acidilactici, Lactobacillus bulgaricus, Lactobacillus plantarum, Lactobacillus acidophilus, Lactobacillus helveticus, Lactobacillus salivarious, Leuconostoc citrovorum, Streptoccus cremoris, Streptococcus diacetylactis*, *Streptococcus lactis*, and *Streptococcus thermophilus* (p. 13, lines 6-11).

The hydrated, edible food item may comprise a liquid, a sauce, or a filled dough product (p. 7, lines 27-30; p. 8, lines 9-12, 17-18; p. 15, lines 15-20). The edible food item may comprise an egg roll (p. 8, line 18), a filled ravioli (p. 8, line 18), juice (p. 8,

lines 10-11), or a dairy product (p. 8, lines 10-11). After pasteurization, the food product may be sealed within a container (p. 15, lines 20-26). Also, the food product may be stored in an anaerobic environment (p. 3, lines 18-20).

Because the microorganisms are encapsulated, the hydration of the culture is slowed and the microorganisms are better protected from inactivation by heat processing during packaging operations (p. 6, lines 3-20). In one embodiment, the encapsulation material dissolves prior to any temperature abuse of the product (p. 10, lines 9-11). In other embodiments, the encapsulation material forms a gel that keeps the microorganisms from dispersing until exposure to temperature above about 10° C., at which point the gel releases the microorganisms (p. 11, lines 17-22).

The encapsulation material may comprise a food item, a fat, an edible polymer, a methyl cellulose material, or a hydroxyl propyl methyl cellulose material (p. 11, lines 2-4, 5, 12, 14-16). The encapsulation material may form a sachet (p. 10, lines 4-5). The encapsulation material may dissolve prior to the food product reaching a temperature state above 10° C. (p. 11, lines 19-21). The encapsulation material may form a gel that keeps the microorganisms from dispersing when the food product is at temperature below 10° C., and wherein the gel releases the microorganisms when the food product reaches a temperature above about 10° C (p. 11, lines 19-21).

The food product may have an initial pH above 5.4 and may comprise nontoxic microorganisms that cause the food product to have a pH of 5.4 within 120 hours at an incubation temperature of 32.2° C. (p. 19, lines 7-9). The food product may comprise greater then about 10^4 CFU/gm of the microorganisms, or from about 10^6 CFU/gm to about 10^8 CFU/gm of the microorganisms (p. 14, lines 10-13). The microorganisms may be provided in a freeze dried culture that is formed into a tablet with a hydroxy propyl methyl cellulose material (p. 26, lines 22-23; p. 27, lines 24-25; p. 28, lines 15-16). Also, the microorganisms may be provided in a freeze dried culture that is placed within a sachet formed from a hydroxy propyl methyl cellulose material (p. 29, lines 18-20).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-10, 12-23 and 30-36 are unpatentable under 35 U.S.C. 103(a) over Hutkins et al. (U.S. Pat. 5,186,962; herein after "Hutkins") in view of Franjione et al. (Franjione, J. and Vasishtha, N., The Art and Science of Microencapsulation, Technology Today, printed from **http://www.swri.org**, 01/03/2008; hereinafter "Franjione") and Gaier (U.S. Pat. 5,645,877; hereinafter "Gaier").

VII. Argument

Rejection of claims 1-10, 12-23 and 30-36 under 35 U.S.C. 103(a) as being unpatentable over Hutkins in view of Franjione and Gaier.

Claims 1-10, 12-23 and 30-36

The present claims relate to food products that are protected against potentially harmful microbial growths by including viable nonharmful bacteria or microorganisms in the food products (p. 5, lines 21-22). The growth of the nonharmful microorganisms helps to inhibit the growth of pathogenic organisms because of competition (p. 7, lines 9-10). The nonharmful microorganisms may also produce by-products that inhibit the growth of harmful microorganisms (p. 7, lines 10-11). The nonharmful microorganisms are selected such that they will inhibit the growth of potentially pathogenic or toxin-producing bacteria if the food product is temperature abused (p. 7, lines 1-3).

The nonharmful microorganisms are encapsulated and dormant up to about 10° C., at which point the microorganisms are released and rendered active (p. 11, lines 17-22). Because the microorganisms are encapsulated, the hydration of the culture is slowed and the microorganisms are better protected from inactivation by heat processing during packaging operations (p. 6, lines 3-20). In one embodiment, the encapsulation material dissolves prior to any temperature abuse of the product (p. 10, lines 9-11). In other embodiments, the encapsulation material forms a gel that keeps the microorganisms from dispersing until exposure to temperature above about 10° C., at which point the gel releases the microorganisms (p. 11, lines 17-22).

Claims 1-10, 12-23 and 30-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hutkins in view of Franjione and Gaier. However, the Examiner has not established a *prima facie* case to support the rejection that the claims were obvious at the time the invention was made.

Claim 1

Claim 1 is the sole independent claim in the rejected claims. The claim recites a food product comprising a pasteurized hydrated, edible food item being at a temperature

state of less than 10° C. The food product comprises encapsulated, dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10° C. If the food product reaches a temperature above 10° C., the nontoxic microorganisms release by-products into the food product that inhibit the growth of harmful microorganisms.

The primary reference, Hutkins, does not disclose providing encapsulated microorganisms, nor dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10° C. Hutkins, in contrast, discloses a food product that contains bacteriocin-producing bacteria that produce the bacteriocin under all conditions, including at refrigeration temperatures (below 10° C.). The bacteriocin is produced specifically without the production of acids, and without changes in pH (col. 12, lines 37-42, 50-55). The bacteria are expressly required to be active at temperatures of 1 ° - 7 ° C. (col. 4, lines 60-63). The skilled artisan would not have a reason to modify the bacteria described by Hutkins to be like those in the present claim 1, because such a modification would destroy a fundamental objective of the reference, which is to have active bacteria at refrigeration temperatures. Similarly, the skilled artisan would not have a reason to modify Hutkins to encapsulate bacteria, because encapsulating the disclosed bacteria would inhibit production of bacteriocin at refrigeration temperatures, which again would destroy the fundamental objective of the reference.

Thus, it is respectfully submitted that claim 1 is not rendered obvious by the Hutkins disclosure. Hutkins does not disclose all of the features of claim 1. In particular, the reference does not disclose the use of dormant, encapsulated microorganisms. In addition, neither Franjione nor Gaier alone or in combination bridge the gap between Hutkins and claim 1. Neither reference discloses dormant, encapsulated microorganisms, as discussed in more detail below. Furthermore, there is no reason or evidence in the references themselves that warrants combining the references as set forth in the Final Office Action.

Franjione is cited for disclosing the use of encapsulation in food products to shield an active ingredient from the surrounding environment (p. 1). The method of encapsulation taught is co-extrusion. The encapsulated, active ingredient may be

released from encapsulation by mechanical rupture, dissolution or melting of the capsule wall or by diffusion through the wall (p. 1). Franjione, however, does not teach encapsulating dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10° C., and wherein, if the food product reaches a temperature above 10° C., the nontoxic microorganisms release by-products into the food product that inhibit the growth of harmful microorganisms. The reference provides no information of any kind that would lead the skilled artisan to encapsulate microorganisms of any kind, let alone microorganisms that are dormant except at certain temperatures. Thus, the reference does not remedy the shortcomings of Hutkins. Furthermore, Hutkins teaches away from a combination with Franjione because encapsulating the bacteria in Hutkins would inhibit production of bacteriocin at refrigeration temperatures, which is desired in Hutkins. Therefore, Franjione does not render claim 1 of the present invention obvious either alone or in combination with Hutkins and Gaier.

Gaier is cited for disclosing the use of *Streptoccocus thermophilus* as a lactic bacteria in preparation of fermented food products (col. 3, lines 38-44). The process described in Gaier is very different from the presently claimed use of microorganisms, however, because Gaier uses the microorganisms to instead produce the food product (col. 1, lines 28-33). There is no reason then to include a dormant stage or to encapsulate the microorganisms during production of the food product. Thus, Gaier does not disclose encapsulating dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10° C., and wherein, if the food product reaches a temperature above 10° C., the nontoxic microorganisms release by-products into the food product that inhibit the growth of harmful microorganisms. Therefore, Gaier does not remedy the shortcomings of Hutkins and Franjione. Additionally, there is no motivation to combine the teachings of Gaier with Franjione and Hutkins because there is no reason to include a dormant stage or encapsulate the bacteria in Gaier. Thus, Gaier does not, alone or in combination with the other references, render claim 1 obvious.

It is, therefore, respectfully submitted that even in combination, Hutkins, Franjione, and Gaier do not disclose all of the features of claim 1, which include being a food product that is at a temperature state of less than 10° C, and that comprises

encapsulated, dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10° C., and wherein, if the food product reaches a temperature above 10° C., the nontoxic microorganisms release by-products into the food product that inhibit the growth of harmful microorganisms. Also, there is no reason provided or evidence found within the references themselves to support combining the references. The function of the primary reference, Hutkins, is destroyed by arbitrarily combining the reference with separate features from the secondary references, Franjione and Gaier, through hindsight reconstruction. A skilled artisan would have no reason to completely change the construction and function of the products of the references in order to combine them and arrive at the presently claimed invention. It does not make sense to combine the references, nor is there any suggestion in the references to combine the references. Hutkins even teaches away from a combination with Franjione. Therefore, Appellants respectfully submit that the Examiner did not establish a *prima facie* case of obviousness in order to render claim 1 unpatentable. Accordingly, reversal of the rejection of record with respect to claim 1 is believed proper and respectfully requested.

Claims 2-10, 12-23 and 30-36

Claims 2-10, 12-23 and 30-36 depend from claim 1 and are similarly patentable over Hutkins in view of Franjione and Gaier, as discussed above with regard to claim 1. Accordingly, reversal of the rejection of record with respect to dependent claims 2-10, 12-23 and 30-36 is also believed proper and respectfully requested.

Conclusion

It is respectfully submitted that the Appellants have shown that the rejections of claims 1-10, 12-23 and 31-36 are unsound and must be reversed. It is also respectfully submitted that that the pending claims are in condition for immediate allowance. Favorable action by the Board and allowance of all claims is, therefore, respectfully solicited

Respectfully submitted,

DAVID J. DOMINGUES, ET AL.

Dated: December 5, 2008

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VIII. Appendix – Claims on Appeal

1. A food product comprising a pasteurized hydrated, edible food item, said food product being at a temperature state of less than 10 ° C, wherein said stored food product comprises encapsulated, dormant, hydrated nontoxic microorganisms that are effectively dormant up to temperatures of about 10 ° C., and wherein, if the food product reaches a temperature above 10 ° C., said nontoxic microorganisms release by-products into said food product that inhibit the growth of harmful microorganisms.

2. The food product of claim 1 wherein the microorganisms, when no longer dormant, inhibit the growth of toxic microorganisms within the food product by producing an acid, thereby lowering the pH of the food product.

3. The food product of claim 1 wherein the microorganisms comprise a bacteria belonging to a genera selected from the group consisting of *Lactococcus, Streptococcus, Leuconostoc, Pediococcus, Lactobacillus, Bifidobacterium*, and *Propionibacterium*.

4. The food product of claim 1 wherein the microorganisms comprise a bacteria selected from the group consisting of *Pediococcus acidilactici, Lactobacillus bulgaricus, Lactobacillus plantarum, Lactobacillus acidophilus, Lactobacillus helveticus, Lactobacillus salivarious, Leuconostoc citrovorum, Streptoccus cremoris, Streptococcus diacetylactis*, and *Streptococcus lactis*.

5. The food product of claim 1 wherein the microorganisms comprise *Streptococcus thermophilus* bacteria.

6. The food product of claim 1 wherein the microorganisms, when no longer dormant, inhibit the growth of toxic microorganisms within the food product by producing one or more antibiotics.

7. The food product of claim 1 wherein the hydrated, edible food item comprises a liquid.

8. The food product of claim 1 wherein the hydrated, edible food item comprises a sauce.

9. The food product of claim 1 wherein the hydrated, edible food item comprises a filled dough product.

10. The food product of claim 1 wherein the food product after pasteurization is sealed within a container.

11. (cancelled).

12. The food product of claim 1 wherein the encapsulation material comprises a food item.

13. The food product of claim 12 wherein the encapsulation material comprises a fat.

14. The food product of claim 1 wherein the encapsulation material comprises an edible polymer.

15. The food product of claim 1 wherein the encapsulation material forms a sachet.

16. The food item of claim 10 wherein the food product is stored in an anaerobic environment.

17. The food product of claim 1 wherein the edible food item comprises an egg roll.

18. The food product of claim 1 wherein the edible food item comprises filled ravioli.

19. The food product of claim 1 wherein the edible food item comprises juice.

20. The food product of claim 1 wherein the edible food item comprises a dairy product.

21. The food product of claim 2, wherein the food product has an initial pH above 5.4 and comprises nontoxic microorganisms that cause the food product to have a pH of 5.4 within 120 hours at an incubation temperature of 32.2° C.

22. The food product of claim 1 wherein the food product comprises greater then about 10^4 CFU/gm of the microorganisms.

23. The food product of claim 1 wherein the food product comprises from about 10^6 CFU/gm to about 10^8 CFU/gm of the microorganisms.

24-30. (cancelled).

31. The food product of claim 1 wherein the encapsulation material comprises a methyl cellulose material.

32. The food product of claim 1 wherein the encapsulation material comprises a hydroxy propyl methyl cellulose material.

33. The food product of claim 1 wherein the microorganisms are provided in a freeze dried culture that is formed into a tablet with a hydroxy propyl methyl cellulose material.

34. The food product of claim 1 wherein the microorganisms are provided in a freeze dried culture that is placed within a sachet formed from a hydroxy propyl methyl cellulose material.

35. The food product of claim 1 wherein the encapsulation material dissolves prior to the food product reaching a temperature state above 10° C.

36. The food product of claim 1 wherein the encapsulation material forms a gel that keeps the microorganisms from dispersing when the food product is at temperature below 10° C., and wherein the gel releases the microorganisms when the food product reaches a temperature above about 10° C.

IX. Appendix - Evidence

There is no evidence to be included in Appendix IX.

X. Appendix - Related Proceedings

There are no related appeals or interferences.